Remarks/Arguments:

The pending claims are 1, 3, 4, 12-14, and 17.

Applicant notes with appreciation the statement of the Examiner that claim 4 would be allowable if rewritten in independent form.

In paragraph 2 of the Office Action, claims 1, 3, 12-14, and 17 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Bobroff et al. (U.S. Patent Application Publication No. 2003/0225373) in view of Dysarz (U.S. Patent No. 5,997,507). This rejection is respectfully traversed.

The Office Action relies upon Bobroff for its teaching of "a base member (914, 916, 918) that forms an acute angle that is approximately 30 degrees." The Office Action's reliance upon this teaching in Bobroff is improper because Bobroff does not have a priority date for those features that is earlier than applicant's priority date.

Applicant's effective filing date is December 19, 2000, the date of his provisional application as stated in paragraph [0002] of the present non-provisional application. However, the priority date of the teaching cited in the Office Action is April 20, 2001.

The face page of the Bobroff '373 publication states that it is a division of Application No. 09/839,052, filed on April 20, 2001, which is a continuation-in-part of Application No. 09/215,356, filed on December 18, 1998. Referring to the Figures in Bobroff, it is seen that reference numbers 914, 916, 918 cited in the Office Action are found only in Figures 53(a) through 53(d). However, Figures 53(a) through 53(d) are not in the '356 application. Therefore, the teaching of Bobroff cited in the Office Action does not constitute prior art to the claims of this application.

For the above reasons, (and for the additional reason that the Office Action failed to establish prima facie obviousness as explained below) claims 1, 3, 12-14, and 17 are not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Bobroff in view of Dysarz.

In paragraph 3 of the Office Action, claims 1, 3, 12-14, and 17 have been rejected under 35 U.S.C. § 103(a) as unpatentable over Safabash et al. (U.S. Patent No. 6,293,925) in view of Dysarz. This rejection fails to establish prima facie obviousness and is respectfully traversed.

Paragraph 3 of the Office Action acknowledges that Safabash "fails to disclose the first release button being substantially normal to the axis of insertion." The Office Action contends that "Dysarz discloses a biasing spring needle catheter with a first release button being substantially normal to the axis of insertion." Consequently, the Office Action contends, it would have been obvious to combine the angled infusion device of Safabash with the release mechanism of Dysarz. The Office Action speculates that this combination could be made by inserting the Dysarz release button into space 159 of Safabash. Applicant respectfully disagrees.

First, one of ordinary skill in the art would not have been motivated to combine the references, and the Office Action fails to point out any motivation other than to suggest that the Dysarz release mechanism allows one hand use. This alleged motivation fails, however, because the Safabash device already allows one hand use. One would not be motivated to seek a one hand release mechanism for a device that is already intended for one hand use.

Further, the divergent of operations of the Safabash and Dysarz devices would discourage any such combination. The Safabash device is an insertion device for automatic placement of an insertion set through the skin of a patient. (col. 1, lines 10-12). When a button is pushed, a plunger is released causing an insertion set to move toward the patient's skin resulting in transcutaneous placement of an insertion needle. In contrast, the Dysarz device is a retraction device. (col. 1, line 60-col. 2, line 10). When its button is pushed, the device retracts a needle from a person's body into a barrel. One of ordinary skill in the art would not be motivated to combine aspects of a retraction device that retracts a needle with aspects of an insertion device that inserts a needle to provide a different insertion device.

Second, it would not have been obvious to combine the push button of Dysarz into the Safabash device because the Dysarz push button would not operate to perform the release function required in Safabash. More specifically, Figures 21 and 23 of Safabash show two trigger fingers 158, each having spring-loaded, resilient trigger arms 156. The trigger fingers 158 are slanted and hook onto trigger slots 159. When the inserter set in Safabash is retracted, trigger fingers 158 engage the trigger slots 159. In order to release the inserter set, button 138 is pushed. Actuator sleeve 188 has a tapered leading edge face 188' (see Figures 22, 23, 25) for engaging both matingly shaped ramped outer faces of trigger fingers 158. When button 138 is pushed, leading edge face 188' of actuator sleeve 188 radially compresses trigger fingers 158 and trigger arms 156 to release plunger 130.

Dysarz, on the other hand, discloses only a single needle release button 9 rather than an actuator sleeve. Using only a single release button would not be sufficient to release the Safabash cannula. A single release button in Safabash would release only one of the trigger fingers 158. The other trigger finger would remain hooked onto the other trigger slot 159, thereby preventing the release of plunger 130. Applying a second Dysarz button to the Safabash device would unnecessarily complicate the Safabash device because a user would have to simultaneously push two buttons, instead of the single button that is contained in the Safabash device.

In addition, a release button in the shape of button 9 in Dysarz would not work in the Safabash device shown in Figure 23. Dysarz button 9 has a portion inside barrel 2 and a portion outside barrel 2. The portion inside the barrel is square shaped, not tapered. See, Figures 2, 4. A square shaped Dysarz button inserted into opening 159 in Safabash would push against either actuator sleeve 188 or against one trigger finger 159. There is no disclosure in Safabash that actuator sleeve 188 is flexible. Accordingly, pressing a Dysarz button against Safabash actuator sleeve 188 would not release the adjacent trigger finger 159. On the other

hand, a Dysarz button pressed against Safabash trigger finger 158 would tend to slide up the tapered shape of trigger finger 158 instead of pushing trigger finger 158 inward. In addition, as noted above, even if a Dysarz button could release one of the Safabash trigger fingers, the other Safabash trigger finger would remain engaged in its own trigger slot 159, thereby preventing release of the Safabash insertion set.

In order to incorporate concepts from Dysarz, the Safabash device would have to be completely redesigned by incorporating two Dysarz buttons and removing actuator sleeve 188. There is no suggestion or motivation contained in the Safabash disclosure or elsewhere in the prior art that would lead one skilled in the art to make such radical changes to the Safabash device. The suggestion for such changes comes only from applicant's disclosure and impermissible hindsight reconstruction. In addition, Safabash's insertion device is designed so that all of its working parts (including its release mechanism) function along a longitudinal axis of its device. (see e.g. col. 2, line 65; col. 3, line 6; col. 3, lines 11-18; col. 9, lines 23-28; col. 13, lines 28-40). It would not have been obvious to totally redesign the Safabash device to substitute something that required a mechanism that operated along an axis that is normal to the longitudinal axis.

For all of the above reasons, claims 1, 14, and 17, along with dependent claims 3, 12, 13, are not subject to rejection under 35 U.S.C. § 103(a) as unpatentable over Safabash in view of Dysarz.

Accordingly, claims 1, 3, 12-14, and 17 are now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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Dated: October 6, 2005

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The Commissioner for Patents is hereby authorized to charge payment to Deposit Account No. **18-0350** of any fees associated with this communication.

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Joshua L. Cohen

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